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Dr. Irene Stith-Coleman  
Office for Human Research Protections  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

July 19, 2002

Dear Dr. Stith-Coleman:

Enclosed are documents detailing a clinical research protocol involving children. My IRB (at the University of North Carolina Medical School) has reviewed this protocol and, while supportive of the research as addressing important questions, did not find the application to be otherwise approvable under 45 CFR 46.404-406 of the Subpart D regulations. Accordingly, the IRB has encouraged me to submit for OHRP review under section 45 CFR 46.407.

It is our understanding that OHRP review under 45 CFR 46.407 is restricted to studies supported by DHHS, so I wish to confirm that this study would be funded by the National Heart, Lung, and Blood Institute under grant no. P50 HL60280 (SCOR in Pathogenesis of Cystic Fibrosis, R. Boucher, P.I.).

Documents enclosed include:

1. The original protocol application (11/16/01)
2. The initial disapproval memo from IRB (2/5/02)
3. My written response to concerns raised in the initial disapproval (3/02)
4. The subsequent disapproval memo from IRB, suggesting submission for OHRP review (4/16/02)
5. A review (which I requested) of this protocol by the national Cystic Fibrosis Foundation's Data Safety Monitoring Board (7/1/02)

Please contact me if other documentation or information is required. My e-mail address is . I look forward to your assessment of this protocol.

Sincerely,

Terry L. Noah, MD  
Associate Professor of Pediatrics